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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/817,198 | 03/27/2001 | Jane Ye | CL001188 | 9081 |

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08/07/2002

CELERA GENOMICS CORPORATION
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EXAMINER

RAWLINGS, STEPHEN L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,198

Applicant(s)

YE ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election facsimile cover sheet*.

DETAILED ACTION

1. The amendment filed July 17, 2002 (Paper No. 4) is acknowledged and has been entered.
2. Claims 1-23 are pending in the application and are currently subject to a restriction and election requirement.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Group I. Claims 1, 2, 20, and 21, drawn to a polypeptide or a fragment thereof, classified in class 530, subclass 350.
 - Group II. Claim 3, drawn to an antibody, classified in class 530, subclass 387.9.
 - Group III. Claims 4-6, 8-11, 22, and 23, insofar as the claims are drawn to a nucleic acid molecule encoding a polypeptide or a fragment thereof, a gene chip comprising said nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell containing said vector, and a method for producing the polypeptide encoded by said nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 1 or shares at least 80% homology with the polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 536, subclass 23.5, 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 70.1.
 - Group IV. Claims 4-6, 8-11, 22, and 23, insofar as the claims are drawn to a nucleic acid molecule encoding a polypeptide or a fragment thereof, a gene chip comprising said nucleic acid molecule, a vector comprising said

nucleic acid molecule, a host cell containing said vector, and a method for producing the polypeptide encoded by said nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 3 or shares at least 80% homology with the polynucleotide sequence set forth in SEQ ID NO: 3, classified in class 536, subclass 23.5, 435, subclass 320.1, class 435, subclass 325, and class 435, subclass 70.1.

Group V. Claim 7, insofar as the claim is drawn to a transgenic non-human animal comprising the comprising a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 800, subclass 10.

Group VI. Claim 7, insofar as the claim is drawn to a transgenic non-human animal comprising the comprising a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 3, classified in class 800, subclass 10.

Group VII. Claim 12, drawn to a method for detecting a polypeptide or fragment thereof, classified in class 435, subclass 7.1.

Group VIII. Claim 13, insofar as the claim is drawn to a method for detecting a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 1, classified in class 435, subclass 6.

Group IX. Claim 13, insofar as the claim is drawn to a method for detecting a nucleic acid molecule, wherein said nucleic acid molecule hybridizes to the complement of the polynucleotide sequence set forth in SEQ ID NO: 3, classified in class 435, subclass 6.

Group X. Claims 14-16, drawn to a method for identifying a modulator or binding agent, classified in class 435, subclass 4.

Group XI. Claims 17 and 18, drawn to a pharmaceutical composition comprising an agent and a method for treating a patient comprising administering to the patient said pharmaceutical composition, which cannot be classified since the chemical and biologic nature of the agent is not disclosed.

Group XII. Claim 19, drawn to a method for identifying a modulator of the expression of a polypeptide, classified in class 435, subclass 4.

4. The inventions are distinct, each from the other because of the following reasons:
Inventions in groups I-VI and XI are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

Inventions in groups III, IV, and VII-XII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in group I and group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as in the process of producing an antibody that binds specifically to said polypeptide.

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Inventions in groups III and IV and groups X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely the host cell can be used in a materially different process of using that product, such as in the process of producing the polypeptide.

The inventions in group I and groups III, IV, VII-IX, XI, and XII are not at all related because the products of group I are not specifically used in any of the steps of the claimed methods in groups III, IV, VII-IX, XI, and XII.

The inventions in groups III and IV and groups VII-IX and XI are not at all related because the products of group I are not specifically used in any of the steps of the claimed methods in groups III, IV, VII-IX, XI, and XII.

The inventions in groups II, V, VI, and XI and groups III, IV, and VII-XII are not at all related because the products of groups II, V, VI, and XI are not specifically used in any of the steps of the claimed methods in groups III, IV, and VII-XII.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

7. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if

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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
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DONNA WORTMAN
PRIMARY EXAMINER

slr

August 5, 2002